

device, unless the foreign establishment ships the device directly to the consumer or patient.

(y) *Person who imports or offers for import* means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001; 77 FR 45940, Aug. 2, 2012]

## Subpart B—Procedures for Device Establishments

### § 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term “device” includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing

of a device intended for human use, including any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party;

(2) Sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person;

(3) Repackages or relabels a device;

(4) Reprocesses a single use device that has previously been used on a patient;

(5) Acts as an initial importer as defined in § 807.3(g), except that initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importer;

(6) Manufactures components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g. blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(c) Registration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in § 807.3(t), and who does not manufacture, repackage, process, or relabel a device.

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-

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based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.26 remain applicable.

(e) Owners and operators of establishments that manufacture devices licensed under section 351 of the Public Health Service Act as well as licensed biological products used in the manufacture of a licensed device must register and list following the procedures set out in part 607 of this chapter, instead of the procedures for registration and listing contained in this part.

[77 FR 45941, Aug. 2, 2012]

### § 807.21 How to register establishments and list devices.

(a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information to us using our electronic device registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section:

(1) Initial establishment registration information as required by §§ 807.22(a) and 807.25;

(2) Updates to registration information as required by §§ 807.22(b) and 807.25;

(3) Initial device listing information as required by §§ 807.22(a), 807.25, and 807.28;

(4) Updates to device listing information as required by §§ 807.22(b), 807.25, and 807.28, including updates to reflect the discontinuance or resumption of the commercial distribution of a previously-listed device as specified at paragraphs (d) and (e) of § 807.28.

(b) If the information under § 807.21(a) cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants must send a letter to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2621, Sil-

ver Spring, MD 20993-0002, that includes the following information:

(1) The name and address of the device establishment(s) to be registered, a contact person for the owner or operator of the establishment, and the telephone number at which that person can be reached. If the establishment has already registered in the past, the letter should also include the owner or operator number, registration number, and any listing numbers previously assigned by FDA for devices manufactured at that establishment.

(2) Information about whether the company is an initial importer as defined in § 807.3(g) and, if so, whether it also conducts any other activities or operations relating to devices.

(3) A statement that use of the Internet is not reasonable for the person requesting the waiver, and an explanation of why such use is not reasonable. The statement must be signed by the owner or operator of the establishment, or by a person employed by the owner or operator who is authorized to make the declaration on behalf of the owner or operator.

(c) Those owners or operators who have obtained a waiver from filing registration and listing information electronically should refer to § 807.34 for information on how to submit such information by postal mail.

(d) When additional device listing information (e.g., copies of labeling or advertisements) is requested by FDA as described at § 807.26(e), such information may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system.

[77 FR 45941, Aug. 2, 2012]

### § 807.22 Times for establishment registration and device listing.

(a) *Initial registration and listing.* An owner or operator of an establishment who has not previously entered into an operation described in § 807.20(a) shall register within 30 days after entering into such an operation and submit device listing information at that time.

(b) *Registration and listing updates.* Owners or operators shall review and